DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3801. Adulteration and misbranding of dextro-amphetamine sulfate tablets and amphetamine sulfate tablets. U. S. v. 232,000 Tablets, etc. Tried to the court. Judgment for the Government. Decree of condemnation and destruction. (F. D. C. No. 31408. Sample Nos. 20953–L, 20987–L, 20988–L.)

LIBEL FILED: On or about August 3, 1951, Northern District of Texas; amended on or about September 21, 1951.

ALLEGED SHIPMENT: On or about January 29, 1951, by the Kumfort Drug Products Co., from Cleveland, Ohio.

PRODUCT: 232,000 *dextro-amphetamine sulfate tablets* and 15,000 *amphetamine sulfate tablets* in labeled and unlabeled bottles at Dallas, Tex., in possession of Ward's Cut Rate Drugs.

Analysis showed that the 232,000-tablet lot contained 5 mg. of a mixture of racemic and dextro-amphetamine sulfate per tablet and that the 15,000-tablet lot contained 6.5 mg. of amphetamine sulfate per tablet.

RESULTS OF INVESTIGATION: The articles were shipped in unlabeled bottles, and portions of both articles were labeled by the consignee.

NATURE OF CHARGE: Adulteration, Section 501 (d), (232,000-tablet lot) a substance, namely, tablets each containing 5 mg. of a mixture of racemic and dextro-amphetamine sulfate, had been substituted for 5 mg. *dextro-amphetamine sulfate tablets*, and (15,000-tablet lot) a substance, namely, 6.5 mg. amphetamine sulfate tablets, had been substituted for 10 mg. *amphetamine sulfate tablets*. Misbranding, Sections 502 (b) (1) and (2), (unlabeled bottles) the articles failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Sections 502 (f) (1) and (2), the labeling of the articles failed to bear adequate directions for use and such adequate warnings against use where their use may be dangerous to health, or against unsafe dosage or duration of administration, in such manner and form, as are necessary for the protection of users. The articles were adulterated and misbranded in these respects when introduced into, while in, and while held for sale after shipment in interstate commerce.

Further misbranding, Section 502 (e) (2), (232,000-tablet lot) the label of the article failed to bear the common or usual name of each active ingredient. The article was misbranded in this respect when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), the label designations, namely, (232,000-tablet lot) "Dextro Amphetamine Sulfate 5 Mg." and (15,000-tablet lot) "Racemic Amphetamine Sulfate 10 Mg.," were false and misleading as applied to articles containing, respectively, 5 mg. of a mixture of racemic and dextro-amphetamine sulfate per tablet and 6.5 mg. of amphetamine sulfate per tablet. The articles were misbranded in these respects while held for sale after shipment in interstate commerce.

DISPOSITION: Ward's Cut Rate Drugs having appeared as interveners, the case came on for trial before the court without a jury, on September 24, 1951. At the conclusion of the trial, the court found that the law and the facts were with the Government, and on September 26, 1951, a decree of condemnation and destruction was entered.